JAN 2 6 2012

510(k) SUMMARY

Eden Spine's Giza® Vertebral Body Replacement

Date:	August 19, 2011
Contact:	Guillaume Viallaneix, CEO Eden Spine, LLC. 377 Maitland Ave. Suite 1015 Altamonte Springs, FL 32701 407-900-9986

Product Class:	Class II
Classification:	21 CFR §888.3060
Product Codes:	MQP
Panel Code:	87

Name of Device and Name/Address of Sponsor

Giza® Vertebral Body Replacement
Eden Spine Co, LLC.
377 Maitland Ave.
Suite 1015
Altamonte Springs, FL 32701
407-900-9986

Common or Usual Name

Spinal intervertebral body fixation orthosis

Device Description

The Giza® is a thoracolumbar vertebral body replacement device. The Giza is comprised of a variety of implant sizes to accommodate various patients' anatomy and pathology, and associated instrumentation. The devices are available in three diameters, 14mm, 21mm and 27mm. The Giza® device can accommodate lordosis from 2-12 degrees and from18 mm to 90mm in height. . All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI).

Predicate Devices

The Giza® was shown to be substantially equivalent to legally marketed predicate devices. These include the VBR by Osteotech (K012254) and the Obelisc VBR by Ulrich GmbH (K060416).

Indications for Use

The Giza® Vertebral Body Replacement is intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g. fracture). The Giza® Vertebral Body Replacement is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (i.e. posterior pedicle screw and rod systems, anterior plate systems,

and anterior screw and rod systems). The use of allograft or autograft with the Giza® Vertebral Body Replacement device is optional.

Technological Characteristics

Performance Data

Static and dynamic axial compression and static torsion were completed following ASTM F2077-03. Static and dynamic torsion was completed per ASTM F2077-03. Subsidence was tested following ASTM F2267-04. Expulsion testing was conducted following a recognized protocol to allow comparison evaluation of intervertebral body fusion device assemblies, and characterize their resistance to expulsion. The above pre-clinical testing performed on the Giza® indicated that the Giza® is substantially equivalent to the predicate devices and is adequate for the intended use. In addition, the Giza® VBR is provided packaged according to ISO 11607 and sterile.

Summary:

The Giza® and predicate devices have the same intended use, to provide mechanical stability by replacing a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g. fracture). The indications for use of the Giza® are exactly the same as the predicate devices. Moreover, the device is very similar in sizes to the predicate devices. The materials used are also the same as in some predicate devices. There are no significant differences in technological characteristics compared to the predicates, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, bench testing demonstrates that these differences do not adversely impact device performance. Eden Spine concludes that the Giza® device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 2 6 2012

Eden Spine, LLC
% Silver Pine Consulting, LLC
Rich Jansen, Pharm.D.
13540 Guild Avenue
Apple Valley, Minnesota 55124

Re: K112429
Trade/Device Name: Giza Vertebral Body Replacement
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: December 21, 2011
Received: December 22, 2011

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

For P/ Acting Deputy Director

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112429

Device Name: Giza Vertebral Body Replacement

Indications for Use:

The Giza® Vertebral Body Replacement is intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g. fracture). The Giza® Vertebral Body Replacement is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The use of allograft or autograft with the Giza® Vertebral Body Replacement device is optional.

Prescription Use ___V____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112429